# APR 17 2009

### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the application of: John E. Walls,

Jeffrey W. Putt, Kenneth E. DeLine

**Application No.:** 10/533,262

**Filed:** April 27, 2005

For: Aqueous Activated Components Conveyed

In A Non-Aqueous Carrier System

Attorney Docket No.: VMACosUSNP

Mail Stop Amendment Commissioner of Patents P.O. Box 1450 Alexandria, VA 22313-1450 **Confirmation No.: 7343** 

**Group Art Unit: 1796** 

Examiner: Kumar, Preeti

## CERTIFICATE UNDER 37 C.F.R. § 1.10 FOR "EXPRESS MAIL"

Date of Deposit: April 17, 2009 Express Mail Label No.: EM335814247US

I hereby certify that this document is being deposited with the United States Postal Service on the date indicated above in an envelope as "Express Mail Post Office to Addressee" service under 37 C.F.R. § 1.10 and addressed to the Commissioner for Patents, P.O. Box

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Justin\Ruth Miles

# DECLARATION OF JOHN E. WALLS UNDER 37 C.F.R. §1.132

Declaration of John E. Walls.

I, John E. Walls, declare as follows:

### I. **BACKGROUND**

1. I am a citizen of the United States residing at 5894 Timberlake Drive, Kentwood, Michigan, USA.

- 2. I obtained a Ph. D. in Chemistry from Fairleigh Dickinson in Madison, New Jersey in 1982 and a Bachelor degree in Chemistry from Pennsylvania State University, University Park, Pennsylvania in 1970.
- 3. Between 1978 and 1988 I was employed by Azoplate, Branchburg, NJ as a Research Chemist and Senior Research Chemist. I relocated to Eastman Kodak in Windsor, Colorado, and between 1988 and 1998 was employed as a Research Chemist, Senior Research Chemist, and Director of Research. During my time at Eastman Kodak, I developed aqueous plate products and computer to plate products and directed the applications department.
- 4. I am listed as an inventor on over 60 issued United States patents and on 69 foreign patents. Many of these are directed to chemical inventions for example computer to plate processes, light sensitive diazonium oligomers, emulsions and microencapsulation.
- 5. During the course of my career, I have obtained extensive experience in working with compositions for the production of microcapsules useful for the encapsulation of a variety of materials in various chemical environments. I consider myself to have more than ordinary skill in the area of producing microcapsules useful for the encapsulation and release of materials from capsules.
- 6. I am one of the inventors of the invention claimed in the above-identified United States Patent application.
- 7. I have read the Office Action mailed October 17, 2008 (the "Office Action") and the references cited by Examiner Nguyen including the MacDonald reference (United States Patent No. 7,053,029), the Rothan reference (French Patent Application No. FR 2717184) and the Rau reference (United States Patent No. 6,310,014).
- 8. I have reviewed the Response and Request for Reconsideration and the listed claims to which this Declaration is attached.

### II. <u>UNITED STATES PATENT NO. 7,053,029 TO MACDONALD.</u>

9. I can say that the MacDonald reference only generally refers to microencapsulation but does not explicitly disclose nor does it impliedly or inherently disclose any information regarding how to make or use any kind of microcapsule. Specifically, the MacDonald reference does not disclose the steps in claim 28 of providing a microcapsule that would satisfy the limitations of "non-aqueous carrier stable capsules" and "rupturing said plurality of capsules by exposure to said amount of water to release said encapsulated material".

10. Based on my experience, I can say that the MacDonald reference does not provide enough information about microcapsules to allow a person of ordinary skill in the field of chemistry to make and use the invention of claim 28.

### III. FRENCH PATENT APPLICATION PUBLICATION 2717184 OF ROTHAN

11. I can say that the Rothan reference discloses a cellulose acetylphatalate film which is not soluble in water. The cellulose acetylphatalate film disclosed by Rothan is not soluble in water due to aromatic groups included in the film's chemical structure. My statement is supported by my experience and by the Merck Manual 8<sup>th</sup> Edition("Merck") which in relevant part is set out below, as follows:

### PRODUCT IDENTIFICATION

HYDROXYPROPYL METHYLCELLULOSE PHTHALATE

CAS NO. 9004-38-0 EINECS NO. unlisted

FORMULA

MOL WT. 80,000 - 140,000

H.S. CODE 3912.39

TOXICITY

**DERIVATION** 

CLASSIFICATION

SYNONYMS Cellacefate: CAP:

Cellulose acetate hydrogen phthalate;

cellulose acetate hydrogen 1,2-benzenedicarboxylate; Cellulose Acetate Monophthalate;

Cellulose Acetylphthalate; Cellulose Acetophthalate; monophthalic acid ester of

hydroxypropyl methyl cellulose; Cellulose acetate phthalate; HPMCP; Hypromellose Phthalate;

PHYSICAL AND CHEMICAL PROPERTIES

PHYSICAL STATE white to off-white powder or flakes

**MELTING POINT** 

**BOILING POINT** 

SPECIFIC GRAVITY

SOLUBILITY IN WATER swells to form viscosity colloidal solution.

SOLVENT SOLUBILITY

Soluble in most organic solvents, Insoluble in hot water, alcohol

DECOMPOSITION pH

VAPOR DENSITY

NFPA RATINGS Health: 1; Flammability: 0; Reactivity: 0

**FLASH POINT** 

STABILITY Stable under ordinary conditions

**APPLICATIONS** 

Hydroxypropyl Methylcellulose Phthalate is an enteric film coating material or a matrix binder in solid dosage forms. It is used as a viscosity control agent, gelling agent, film former, stabilizer, dispersant, lubricant, binder, emulsifying agents, and suspending agent. End applications include adhesives and glues, agriculture, building materials, personal care products, detergents and surfactants, paints, printing inks, and coatings, pharmaceuticals, food products, polymerization and textiles.

SALES SPECIFICATION

**APPEARANCE** 

white to off-white powder

Hydroxypropyl content 5.0 - 10.0%

Methoxyl content 18.0 - 24.0% PHthalyl content 2.0% max

- 12. The Merck also makes clear that decomposition of cellulose acetylphatalate is based on change of pH which is consistent with the disclosure of the Rothan reference.
- 13. I have also read the Examiner's statement in the Office Action on Page 3 that "it would have been obvious to one of ordinary skill in the art to have substituted the cellulose with its homologues because characteristics normally possessed by members of homologous series are principally the same (e.g. water soluble). . .chemists knowing properties of one member of series would in general know what to expect in adjacent member, . . .."
- 14. I can say that the properties of the cellulose acetylphatalate film disclosed by Rothan and many homologues are not principally the same as, and are unlike the properties of, the

cellulose capsules listed in the specification of the above-identified patent application at page 13, lines 4-5. Additionally, solubility is affected by acetyl value. The triacetate is insoluble in water, alcohol, ether, but soluble in glacial acetic acid. The tetraacetate is insoluble in water, alcohol, ether and glacial acetic acid. The pentaacetate is insoluble in water, but soluble in alcohol.

- 15. Based on my experience, a chemist would not generally know from the disclosure of the cellulose acetylphatalate film in Rothan that the cellulose capsules listed in the specification would be water soluble because the cellulose acetylphatalate film disclosed by Rothan being insoluble in water would lead away from rather than toward that conclusion.
- 16. I can say from my review of the Rothan reference and my experience that the disinfectant soap disclosed by Rothan is an aqueous disinfectant soap because Rothan discloses the pH of the disinfectant soap and use of the cellulose acetylphatalate film for the microcapsules is consistent with the function of avoiding rupture of the microcapsules when mixed in the aqueous disinfectant soap.
- 17. I can also say from my review of Rothan that this reference provides only a general teaching with regard to encapsulation and does not provide any working examples of encapsulation and in my opinion a person of ordinary skill in the chemical arts could not make a soap with encapsulated dye which functions as generally envisioned by Rothan without undue experimentation. For example, a person of ordinary skill in the art in view of the general teaching of Rothan with regard to the use of the cellulose acetylphatalate film would be faced with finding an antiseptic soap having a composition which is sufficiently inorganic and having a suitable pH in which the Rothan film would be stable and then developing a method of changing the pH of the soap to predictably decompose the film during hand washing to release the dye to indicate that a proper period of time for hand washing has elapsed.

### IV. THE COMBINATION OF MACDONALD AND ROTHAN

- 18. I have also read the Examiner's statement in the Office Action on Page 3 that "Because the references teach the similar methods and elements, the claims would be obvious because the substitution of one known element for another would have yielded predictable results to one of ordinary skill in the art at the time of the invention."
- 19. I can say based on my review of the MacDonald and Rothan references as above declared in Paragraphs 8-16 of this Declaration that the combination of MacDonald and Rothan does not teach similar methods and elements as the invention of claim 28-35 and the claims dependent thereon. MacDonald does not in my opinion teach any methods or elements of microencapsulation and certainly does not teach the method or elements of claims 28-35. Combining MacDonald with Rothan would lead a person of ordinary skill in the chemical arts away from not toward the elements of the invention of claim 28 because Rothan discloses an aqueous disinfectant soap rather than a non-aqueous carrier as claimed and decomposition of a film dependent on pH change rather than decomposition by exposure to water as claimed.
- 20. I have also read the Examiner's statement in the Office Action on Page 3 that "Furthermore, the claims would have been obvious because a particular known technique was recognized as part of the ordinary capabilities of a skilled artisan."
- 21. I can say based in part on facts set out in my declarations made above that the combination of MacDonald and Rothan does not make known the steps of claims 28-35, rather as above declared the combination of MacDonald and Rothan would lead one of ordinary skill in the chemical arts away from the invention.
- 22. Moreover, I can say that because many of the embodiments of the MacDonald technology teach that "indicators may be activated through changes in pH" (see for example MacDonald at Column 3, lines43-45) that the cellulose acetylphatalate film or homologues thereof would be inoperable or require more than routine experimentation to produce a

substantial redesign of the Rothan film which would be useful with embodiments of the MacDonald technology. In any event, even if the Rothan film could be used in certain embodiments taught by MacDonald none would encompass all the steps and elements of claimed invention of claim 28.

23. I can further say that MacDonald teaches thousands of possible combinations of "first component" and "second component" soaps as defined (see MacDonald at Column 1, lines 65-66 through Column 2, lines 1-2) each having unique chemical features such as pH, solvation, activation, miscibility and the like. MacDonald does not provide a single working example or any detailed guidance as to how to make or use any possible combination of the first component or the second component in a microencapsulated formulation. Similarly, Rothan teaches many different combinations of chemicals which can be mixed together to achieve results similar to those described by MacDonald; however, provides only general guidance as to how to make and use a combination in the context of microencapsulation and even that general guidance teaches away or would lead a person of ordinary skill in the art away from the claimed invention. In my opinion, the combination of MacDonald and Rothan simply affords the person of ordinary skill in the art an opportunity for endless experimentation which may or may not result in a soap which separates two components by microencapsulation which when mixed by rupture of the microcapsule during the procedure of hand washing produces an indication that the desired period of hand washing has elapsed.

## V. <u>UNITED STATES PATENT 6,310,014 TO RAU</u>

- 24. I can say based on my experience that Rau describes an embodiment of a gasified solid component which is a blend of sugar, glucose, and lactose which is very soluble in water.
- 25. I can further say Rau discloses that "liquid products are generally suspensions of gasified solid. The liquid phase must be virtually anhydrous to prevent premature dissolution of the gasified solid." (see Rau, Col. 3, lines 26-39). Rau provides a list of compositions

which can be obtained in a virtually anhydrous form such as mineral oils, alcohols, propylene glycol, and the like (see Rau, Col. 3, lines 31-39).

26. I can further say that Rau does not disclose any detailed guidance or working example of any liquid soap which contains gasified solids. All the working examples of the Rau are admixtures of gasified solids with dry materials or admixtures of dry materials on which an amount of liquid can be absorbed to provide stability of the gasified solid.

### VI. THE COMBINATION OF MACDONALD, ROTH, AND RAU.

- 27. I have also read the Examiner's statement in the Office Action on Page 4 that "Because the references teach the similar methods and elements, the claims would be obvious because the substitution of one known element for another would have yielded predictable results to one of ordinary skill in the art at the time of the invention."
- 28. I can say based on my review of the MacDonald, Rothan, and Rau references as above declared in Paragraphs 1-26 of this Declaration that the combination of MacDonald. Rothan and Rau does not teach similar methods and elements between them or as to the method of claim 28. MacDonald does not in my opinion teach any working examples or detailed guidance as to any methods or elements of microencapsulation and certainly does not teach the method or elements of claims 28-35. Rau teaches methods and elements which are entirely dissimilar to MacDonald and Rothan. In particular, one of ordinary skill in the art would know that the gasified solids of Rau cannot be substituted for cellulose acetylphatalate film (insoluble to water) encapsulated dye disclosed by Rothan because the gasified solids described by Rau would rapidly decompose in the disinfectant soap disclosed by Rothan thereby rendering the composition of Rothan inoperable for its intended purpose. Similarly, one of ordinary skill would know that the gasified solids of Rau cannot be predictably substituted into MacDonald because the many combinations of first components and second components described by MacDonald occur in chemical environment sufficiently aqueous to decompose the gasified solid described by Rau making these embodiments of the MacDonald reference inoperable. In my opinion, substitution of the Rau gasified capsules

into either of the MacDonald or the Rau compositions would not yield predictable results to one of ordinary skill in the art.

- 29. I have also read the Examiner's statement in the Office Action on Page 4 that "Furthermore, the claims would have been obvious because a particular known technique was recognized as part of the ordinary capabilities of a skilled artisan. In particular, it would have been well within the purview of skill artisan to implement the feature of a water soluble envelope with fragrance and dye ingredients to gain the benefits of a time dependence release mechanism that has a pleasant sensorial perception"
- 30. I can say that if the Examiner is referring to Rothan as the base device and to Rau as the comparable device that was improved in the same way as the claimed invention, that a person of ordinary skill in the art could not have applied Rau to Rothan with predictable results. As declared above, placing the gasified solid into Rothan would simply result in decomposition of the gasified solid making Rothan inoperable as a soap.
- 31. I can say that if the Examiner is referring to MacDonald as the base device and to Rau as the comparable device that was improved in the same way as the claimed invention, that a person of ordinary skill in the art could not have applied Rau to MacDonald with predictable results. As declared above, MacDonald does not describe a first component and a second component each virtually anhydrous in which the gasified solid would remain stable. Placing gasified solid into the MacDonald reference would make MacDonald inoperable for its intended purpose as a soap that provides an observable change after a period of time.
- 32. I can also say that in my experience even if the Rau gasified solids are placed into virtually anhydrous liquids that most of these liquids would not be useful separately as hand wash compositions. As examples, anhydrous liquids disclosed by Rau such as corn oil, avocado oil, safflower oil, mineral oil, petrolatum, ethanol, isopropanol, butanol would not be utilized separately as hand wash compositions. Also, even if these compositions are obtained virtually anhydrous as required by Rau, these compositions would be sufficiently hygroscopic to accumulate sufficient water to degrade the gasified solids in part or in whole.

Substituting dye as described by either of the Rothan reference or MacDonald reference for gas in the gasified solid would simply lead to a discoloration of the liquid over a relatively short period of time making the MacDonald or the Rothan references inoperable for the intended purpose of indicating change of color during use of the composition.

- 33. I can also say that Rau would not be utilized by a person of ordinary skill in the art for the purpose of providing a predictable time dependence release mechanism for a variety of reasons. First, Rau does not provide any teaching that the gasified solids can be used as a predictable time dependence release mechanism. Rau discloses that when mixed with water "a crackling sound can be heard for about 4 minutes" (see for example Rau, Column 5, lines 66-67). This result does not afford any predictable time dependence as to release of the gas or of any dye which would occur after a period of time as described by MacDonald or Rothan.
- 34. I have read the Examiner's statement that the MacDonald reference "teaches the features of dye release agent such as via microencapsulation and features of a non-aqueous liquid component."
- 35. I can say that MacDonald does not disclose the "features of a non-aqueous liquid". McDonald teaches only "an over-the-counter liquid soap, Kimberly-Clark Professional antibacterial Clear Skin Cleanser (PCSC C2001-1824)". However, disclosure of the trademark or trade name of the Clear Skin Cleanser product does not teach the composition of the product. The trademark or trade name of a product may remain consistent over time while the composition may not. Therefore, it is not possible to know the features of the Clear Skin Cleanser at all based on what is taught by the McDonald reference.
- 36. I can say that MacDonald generally teaches without any detailed guidance or working examples that "components may be kept separate until washing has begun or may be mixed in a manner such that the change does not occur until washing. Thus the components may be kept in two part dispenser or may be kept together with one component inactive by some means, such as microencapsulation". In my opinion a person of ordinary skill in the art

would not be able to make and use a microencapsulated dye release agent from the description of MacDonald. To the extent that the Examiner asserts that MacDonald teaches more I would disagree.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. §1001 and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

John E. Walls

Date: